AUG 10 2011

9. 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K111963

Applicant Information:

Date Prepared: July 8, 2011

Name: BridgePoint Medical
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Plymouth, MN 55441
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Contact Person: Jill Munsinger
Phone Number: office: 763-225-8510 / cell: 651-270-0572
E-mail: jmunsinger@bridgepointmedical.com

Device Information:

Classification: Class II Percutaneous Catheter
Trade Name: Mantaray™ Catheter
Common Name: Percutaneous Catheter
Classification Name: Percutaneous Catheter

Predicate Devices:

The BridgePoint Medical Mantaray™ Catheter is substantially equivalent in intended use, method of operation and technical aspects to the following predicate device:

K080987 and K101591 – Stingray™ Catheter

Device Description:

The Mantaray™ Catheter is a single use, over-the-wire, disposable, dual lumen percutaneous catheter that facilitates the placement, support and steering of a guidewire into discrete regions of the peripheral vasculature through the central guidewire lumen or through one of two sideports (identified by radiopaque markers). The sideports connect with the central guidewire lumen and facilitate guidewire steering (at an angle to the central lumen) by allowing the guidewire to exit the catheter. The catheter contains a small non-compliant balloon segment used for fluoroscopic orientation on the distal tip of the flexible shaft.

Intended Use:
The BridgePoint Medical Mantaray™ Catheter is indicated for directing, steering, controlling, and supporting a guidewire in order to access discrete regions of the peripheral vasculature.

Comparison to Predicate Device(s):
The Mantaray™ Catheters are substantially equivalent to the Stingray™ Catheters, K080987 and K101591 in that they are both designed to direct, steer, control and support a guidewire in accessing discrete regions of the peripheral vasculature.

The Mantaray™ Catheter is constructed of the same materials as the Stingray Catheter. Modifications were made to the balloon size and proximal shaft stiffness. The Stingray™ Catheters and Mantaray™ Catheters are manufactured using the same processes and components and have similar physical attributes (balloon performance, trackability, tensile, radiopacity, and torque, etc.).

Both devices include radiopaque markers located within the balloon segment to indicate the location of the guidewire lumen ports.

Performance Data:
The Mantaray™ Catheters have been evaluated using the following *in vitro* bench testing to confirm the performance characteristics as compared to the predicate device:

- Tensile
- Burst
- Fatigue
- Inflation & Deflation Time
- Dimensional
- Guidewire Insert & Withdrawal
- Flexibility
- Trackability
- Guidewire Re-Direction
- Markerband Movement & Removal
- Markerband & Guidewire Interaction
- Kink Resistance
- Coating
- Torque
- Surface Defects
- Corrosion Resistance
- Luer and Hub Tests
- Balloon Protector Removal, and
- Radiopacity

In vivo testing was also completed in accordance with 21 CFR Part 58, "Good Laboratory Practices for Nonclinical Laboratory Studies." The functional performance and safety of the Mantaray™ Catheters were evaluated in a porcine animal model. Mantaray™

Catheters were inserted into four arteries in each of six animals used for the evaluation. The vessels were evaluated angiographically followed by histology and pathology. Hematology and serum chemistry along with gross necropsy were also used for evaluations. There were no reported complications during each treatment. All six-animals survived the in-life period with no angiographic evidence of vessel injury or downstream embolism and no abnormal pathologic findings.

Biocompatibility testing on the Mantaray™ Catheters was not completed as all materials are included in the predicate device, Stingray™ Catheter. Biocompatibility testing was successfully completed previously and demonstrated the materials used in the design and manufacture of the device are non-toxic and non-sensitizing to biological tissues consistent with the intended use. The following Biocompatibility tests were previously completed:

- Cytotoxicity L929 MEM - ISO
- Kligman Sensitization (Maximization) - ISO
- Irritation- Intracutaneous Injection - ISO
- Acute Systemic Cytotoxicity - ISO
- Pyrogen – ISO
- Hemocompatibility - (Direct and Indirect) Hemolysis - ASTM
- *In Vitro* Hemocompatibility Assay - ISO
- Complement Activation (Direct) Assay - ISO
- *In Vivo* Thrombogenicity Assay - ISO, and
- Unactivated Partial Thromboplastin Time - ISO

All test results demonstrated the materials, manufacturing processes, and design of the Mantaray™ Catheters met the established performance criteria and will perform as intended.

Summary:

Based upon the intended use and descriptive information provided in this pre-market notification, the BridgePoint Mantaray™ Catheters have been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BridgePoint Medical, Inc.
C/O Jill Munsinger
2800 Campus Drive, Ste. #50
Plymouth, MN 55441

AUG 10 2011

Re: K111963
Trade/Device Name: Mantaray™ Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 08, 2011
Received: July 11, 2011

Dear Ms. Munsinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

8. INDICATIONS FOR USE STATEMENT

510(k) Number: (TBA)

Device Name: **BridgePoint Medical Mantaray™ Catheter**

Indications For Use:

The BridgePoint Medical Mantaray™ Catheter is indicated for directing, steering, controlling, and supporting a guidewire in order to access discrete regions of the peripheral vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111963